UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Alliance for Hippocratic Medicine, *et al.*, Plaintiffs, *v.* U.S. Food and Drug Administration, *et al.*, Defendants.	Case No. 2:22-cv-00223-Z

DEFENDANTS' OPPOSITION TO THE STATES OF MISSOURI, KANSAS, AND IDAHO'S MOTION TO INTERVENE

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7C Charles A. Wright et al., Federal Practice & Procedure § 1918 (3d ed. Apr. 2023) 4

Abortions in Kansas, 2020 Preliminary Report,
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Abortions in Kansas, 2021 Preliminary Report,
https://perma.cc/3CQ6-SFNE 12

Abortions in Kansas, 2022 Preliminary Report,
https://perma.cc/L5XC-4JT2 12

Mail-order abortion pill requests surged after Roe reversal, study finds, AXIOS, Nov. 1, 2022, https://perma.cc/6BDZ-3Z9D 13

Nearly half of abortions in Kansas are for Missouri residents, THE KANSAS CITY BEACON, Nov. 17, 2021, https://perma.cc/H5HA-5GCK 12

To get banned abortion pills, patients turn to legally risky tactics, THE WASHINGTON POST, July 6, 2022, https://perma.cc/K8Z9-VV35 13

The States of Missouri, Idaho, and Kansas seek to intervene in this case almost a year after it was filed, after the Supreme Court has granted certiorari, for the express purpose of remedying jurisdictional defects in the existing Plaintiffs' standing—failures the U.S. Food & Drug Administration (FDA) has emphasized since its initial filing in this case. The Court should deny this belated request, for several reasons.

First, granting the States' intervention motion would be futile. The States seek to intervene because they claim that their presence in the case can cure defects in Plaintiffs' standing. But as previously explained, jurisdiction over a case must be established at the outset of litigation, so if Plaintiffs did not possess standing when the case commended, that defect cannot be cured by the later intervention of new parties. Moreover, the States' own theories of standing fail as a matter of law, further highlighting that their participation could not allow this case to proceed.

Second, even apart from jurisdiction, the States do not make the showing necessary to support intervention. The States attempt to justify their extreme delay by pointing to three events this past summer that, they say, newly apprised them of an interest in this litigation. But each of those events was either not new or not relevant to this litigation, and therefore cannot excuse the States' untimely request to participate. Moreover, the States' asserted interest in this litigation is illusory because resolution of Plaintiffs' claims will not directly impact any of the States; for similar reasons, denying intervention cannot possibly impair or impede the States' ability to protect any legally cognizable interest. And the States also cannot rebut the strong presumption that the existing Plaintiffs adequately protect their asserted interests, since both groups seek the same relief in this lawsuit and the States cannot articulate any adversity of interest between them. In short, the States do not meet any of the factors for intervention as of right, and for similar reasons cannot establish any reason to grant permissive intervention. To the extent the Court does not await the outcome of Supreme Court merits proceedings before ruling, the motion for intervention should be denied.

BACKGROUND

Plaintiffs filed suit and sought a preliminary injunction on November 18, 2022. *See* ECF Nos. 1, 8. On April 7, 2023, this Court granted in part Plaintiffs' motion and stayed the effective

date of the challenged agency actions. *See* ECF No. 137. That same day, both FDA and Intervenor-Defendant Danco Laboratories, LLC filed notices of appeal. *See* ECF Nos. 138, 139. The United States Court of Appeals for the Fifth Circuit issued a partial stay of this Court's order on April 12, 2023, *see* No. 23-10362, 2023 WL 2913725, and on April 21, 2023, the Supreme Court fully stayed that same order pending resolution of Supreme Court proceedings in this case. *See Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023). This Court's order thus never has taken effect. On August 16, 2023, the Fifth Circuit resolved the merits of the appeal, vacating in part and affirming in part this Court's order. *See All. for Hippocratic Med. v. FDA*, 78 F.4th 210 (5th Cir. 2023).

Both FDA and Danco filed petitions for a writ of certiorari on September 8, 2023, Supreme Court Case Nos. 23-235, 23-236, seeking review to determine Plaintiffs' Article III standing, likelihood of success on the merits of the FDA actions as to which the Fifth Circuit affirmed this Court's order, and the appropriate scope of relief, if any. On October 12, 2023, Plaintiffs filed a conditional cross-petition for certiorari presenting additional questions regarding those claims as to which the Fifth Circuit vacated this Court's order. Supreme Court Case No. 23-395. On December 13, 2023, the Supreme Court granted FDA's and Danco's petitions for certiorari, in time for the case to be argued and decided this term, and denied Plaintiffs' cross-petition.

In the meantime, the States of Missouri, Kansas, and Idaho filed a motion to intervene as plaintiffs in this action on November 3, 2023, nearly one year after litigation commenced. *See* ECF No. 151. The States ground their asserted need to intervene on FDA's consistent arguments that the existing Plaintiffs lack standing: Because the States seek to press what they describe as "sovereign and economic harms that cannot be asserted by private plaintiffs," they contend their intervention will "ensure[] that this Court (or appellate courts) can more cleanly get to the merits of this" case. ECF No. 152, Suggestions in Supp. of Mot. to Intervene ("Mot."), at 1.

DISCUSSION

I. Granting Intervention Would Be Futile Given this Court's Lack of Jurisdiction.

A. The States Cannot Rehabilitate the Plaintiffs' Lack of Standing.

FDA consistently has argued throughout this litigation that the existing Plaintiffs lack standing. *See* ECF No. 28, Defs.' Opp'n to Mot. for Prelim. Inj., at 8-16; Application for Stay, No. 22A902, 2023 WL 3127519 (Apr. 14, 2023); Br. for Fed. Appellants, No. 23-10362, 2023 WL 3273780 (5th Cir. Apr. 26, 2023); Pet. for Cert., No. 23-235. Almost a year into litigation, the States now seek to intervene in an effort to remedy those jurisdictional defects. *See* Mot. at 1, 5. But the States cannot salvage the Plaintiffs' lack of standing because jurisdiction is measured at the outset of litigation—and if the existing Plaintiffs lack standing, the States cannot proceed in this district, because the case would have to be dismissed or transferred for improper venue.

As previously explained, it is "well-settled that '[a]n existing suit within the court's jurisdiction is a prerequisite of an intervention, which is an ancillary proceeding in an already instituted suit.'" *Harris v. Amoco Prod. Co.*. 768 F.2d 669, 675 (5th Cir. 1985) (quotation omitted); *see* ECF No. 155, Mot. to Hold in Abeyance the Mot. to Intervene, at 4-5; ECF No. 158, Reply Mem. in Supp. of Abeyance, at 4-7. Because the Federal Rules of Civil Procedure cannot extend the jurisdiction of any court, "[i]ntervention cannot cure any jurisdictional defect that would have barred the federal court from hearing the original action." 7C Charles A. Wright et al., Federal Practice & Procedure § 1917 (3d ed. Apr. 2023). Consequently, if the existing Plaintiffs are held to lack standing, the States cannot vest this Court with jurisdiction to reach the merits.

These principles apply regardless of whether this Court rules on the intervention request before or after any ruling on standing from the Supreme Court. *See* ECF No. 158 at 4-6; *Disability Advocs., Inc. v. N.Y. Coal. for Quality Assisted Living, Inc.*, 675 F.3d 149, 160-62 (2d Cir. 2012) (noting agreement on this "deeply entrenched" jurisdictional principle in every circuit to have reached the question); *Summit Off. Park, Inc. v. U.S. Steel Corp.*, 639 F.2d 1278, 1282 (5th Cir. 1981) ("where a plaintiff never had standing to assert a claim against the defendants, it does not have standing to amend the complaint and … substitute[e] new plaintiffs, a new class, and a new cause of action"); *Kendrick v. Kendrick*, 16 F.2d 744, 745-46 (5th Cir. 1926) ("An existing suit within the court's jurisdiction is a prerequisite of an intervention … The intervening petition being 'merely a

contrivance between friends for the purposes of founding a jurisdiction which otherwise would not exist, the device cannot be allowed to succeed.'") (citation omitted); *Aetna Cas. & Sur. Co. v. Hillman*, 796 F.2d 770, 776 (5th Cir. 1986) (holding that the existence of jurisdiction "at the *commencement* of the action is controlling … and subsequent actions do not affect the court's jurisdiction. Jurisdiction cannot be created retroactively by substituting a diverse claimant for a nondiverse party." (citations omitted)); *Walters v. Edgar*, 163 F.3d 430, 432-33 (7th Cir. 1998) (holding "federal jurisdiction never attached" if "plaintiffs never had standing to bring this suit," a failure that cannot be cured through addition of new parties).

Nor could the States independently proceed with their claims in this Court, given their inability to satisfy venue. *See* ECF No. 155 at 4-5; ECF No. 158 at 7-8. In the scenario posited by the States, in which the Supreme Court determines that Plaintiffs lack standing, this suit must be dismissed or transferred regardless of the merits of the States' intervention request, since an intervenor in that situation must "satisf[y] by itself the requirements of jurisdiction and venue," Federal Practice & Procedure § 1918. *Cf. Georgia Republican Party v. Sec. & Exch. Comm'n*, 888 F.3d 1198, 1205 (11th Cir. 2018) (transferring case to proper court where only party satisfying venue lacked standing).

In short, the States cannot escape the "deeply entrenched" principle that "intervention will not be permitted to breathe life into a 'nonexistent' lawsuit." *Disability Advocs., Inc.*, 675 F.3d at 160 (citation omitted). At a minimum, these jurisdictional issues underscore that the Court may wish to await the outcome of Supreme Court proceedings before ruling on this motion.

B. <u>The States Independently Lack Standing to Pursue Their Claims.</u>

Even apart from the States' inability to manufacture jurisdiction if Plaintiffs lack standing, allowing intervention would be futile for yet another reason: The States have not adequately established their own Article III standing to pursue their claims. Specifically, the States rely on three claimed injuries: purported economic harms stemming from complications after certain individuals take mifepristone; sovereign harms to the States' ability to enforce their legal codes; and quasi-

sovereign interests in preventing harm to their citizens. But none of these alleged injuries satisfies Article III, as previewed here (and as FDA would demonstrate in a motion to dismiss, if necessary).

Even if the Supreme Court were to uphold the Fifth Circuit's determination that Plaintiffs have standing, the States *still* must demonstrate standing to the extent they seek relief beyond that currently sought by the existing Plaintiffs. *See Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017). Here that would mean, at minimum, establishing standing to seek rescission of FDA's 2019 approval of the generic version of mifepristone, *see* Prop. Compl. ¶¶ 407-15, which under current Fifth Circuit precedent Plaintiffs lack standing to challenge.

To demonstrate Article III standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). To establish injury in fact, the States are required to show "an invasion of a legally protected interest" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (citation omitted). None of the States' theories suffice.

1. The States cannot rely on indirect and speculative economic harms.

The States first allege that FDA's decisions have "inflict[ed] substantial economic injury on [Movant] States," Prop. Compl. ¶ 261, through the provision of emergency care for Medicaid recipients experiencing complications after taking mifepristone, *id.* ¶¶ 278-300, through unrecompensed costs for providing that same care at public hospitals, *id.* ¶¶ 301-06, and through mental health care purportedly provided through public insurance for patients who took mifepristone, *id.* ¶¶ 307-15.

This theory is incompatible with the Supreme Court's recent decision in *United States v. Texas*, 143 S. Ct. 1964 (2023). There, two states asserted standing to challenge federal immigration-enforcement guidelines on the theory that the guidelines "impose[d] costs on the States," because they would make expenditures to "continue to incarcerate or supply social services such as healthcare and education to noncitizens." *Id.* at 1969. Although the district court had accepted that

theory, the Supreme Court reversed, explaining that the states' challenge to the enforcement guidelines was "not the kind redressable by a federal court," *id.* at 1971, and emphasizing that "federal courts must remain mindful of bedrock Article III constraints in cases brought by States against an executive agency or officer," *id.* at 1972 n.3. In particular, the Court criticized as "attenuated" theories of state standing resting on claims that a federal policy "has produced only" "indirect effects on state revenues or state spending." *Id.* "[I]ncidental and attenuated harm is insufficient to grant a state or county standing." *El Paso Cnty., Texas v. Trump*, 982 F.3d 332, 341 (5th Cir. 2020); *see also, e.g.*, *Arizona v. Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (a "boundless theory of standing," "in which all peripheral costs imposed on States by actions of the [federal government] create a cognizable Article III injury," "'would make a mockery … of the constitutional requirement of case or controversy'").

The States' assertion of economic harm matches precisely the sort of harm that the Supreme Court described as "attenuated," *Texas*, 143 S. Ct. at 1972 n.3. The States do not claim that FDA has directly imposed costs on them, and instead argue that they will make additional expenditures because of FDA's failure to regulate others (*e.g.*, the sponsors of mifepristone) more strictly and the resulting decisions of private parties. Specifically, the States suggest that FDA's modification of mifepristone's conditions of use, including relaxation of certain restrictions on access, makes their citizens more likely to obtain the medication within or outside their borders, and to the extent their citizens experience an extremely rare serious adverse event and require medical care as a result, the State might wind up paying for that care under Medicaid (or a state-subsidized hospital might provide less-than-fully-compensated care). Federal courts lack jurisdiction to address alleged harms whose connection to the challenged policy is so speculative and indirect, given that "federal policies frequently generate indirect effects on state revenues or state spending." *Id.*

In addition to being legally foreclosed, there are also serious reasons to doubt the factual plausibility of the States' theories. For instance, despite the large numbers of women who have taken mifepristone, Idaho identifies only a *single example* of a state Medicaid recipient ever having been treated for "bleeding following a failed medication abortion," Prop. Compl. ¶ 295. And

although Idaho claims to have expended several thousand dollars in state funds in 2019 and 2022 "covering treatment and follow-up care for abortion medical complications," *id.* ¶¶ 296-97, it does not specify whether the relevant abortions actually involved mifepristone, let alone provide any basis for concluding that Idaho would have avoided those expenditures if FDA's 2016 and later actions were invalidated and mifepristone was available only under the pre-2016 conditions of use. (That is the necessary showing the States must make, given that they do not challenge the underlying 2000 approval, and instead challenge only FDA's actions from 2016 and beyond.) Such threadbare allegations suggestive, at most, of isolated instances of past harm fall far short of demonstrating certainly impending future injury. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013).

Equally insufficient is Missouri's speculation that, "*[i]f* a public hospital provides medical services for complications stemming from" mifepristone and does not receive full reimbursement from state Medicaid, that facility could suffer a loss; nowhere does Missouri allege that its Medicaid reimbursement rate for such treatment is, in fact, lower than its public hospitals' costs or that those hospitals have even experienced a loss when treating past complications. *See* Prop. Comp. ¶¶ 301-06 (emphasis added). And Kansas makes no attempt whatsoever to allege concrete economic harms. These defects (and others, to be addressed in a motion to dismiss, if necessary) underscore that the States' claimed economic harms are neither legally nor factually cognizable.

2. The States have not established a threat to their sovereign interests.

The States next allege that "FDA's actions interfere with [the] States' 'sovereign interest in the power to create and enforce a legal code,'" Prop. Compl. ¶ 322 (citation omitted), in two ways. Neither is sufficient to establish standing.

First, the States suggest that a court might regard FDA's elimination of the in-person dispensing requirement as preempting Missouri's laws governing the dispensing of mifepristone and other drugs that induce abortions. But the States fail to identify any actual or imminent controversy over whether their laws are preempted; they simply point to a recent decision of a district court addressing West Virginia's laws. *GenBioPro, Inc. v. Sorsaia*, 2023 5490179 (S.D. W. Va. Aug. 24, 2023). The States cannot establish standing to challenge FDA's action on the theory that

someone, at some point, in some other case might rely on that action to argue that their laws are preempted. *See, e.g.*, *Bauer v. Texas*, 341 F.3d 352, 358 (5th Cir. 2003) (standing to seek equitable relief cannot be based on a "conjectural, hypothetical, or contingent" dispute; there must be a "real and immediate" controversy over "a definite, rather than speculative threat of future injury").

Second, the States claim sovereign harms in FDA's actions allegedly "interfer[ing] with the fundamental policy of States like Missouri to prohibit abortions (other than in exceptional circumstances) and to require in-person administration of abortion drugs," Prop. Compl. ¶ 325—in other words, that FDA's actions purportedly make it easier for others to evade state law. But this theory cannot be squared with the Supreme Court's decision in *United States v. Texas*, in which the district court found state standing based on the assertion that a federal policy led to individuals "committing[] more crimes in Texas," 606 F. Supp. 3d 437, 467 (S.D. Tex. 2022), but the Supreme Court then reversed, concluding that "none of the various theories of standing asserted by the States … overcomes the fundamental Article III problem with this lawsuit." 143 S. Ct. at 1972 n.3. The Supreme Court consistently has refused to "endorse standing theories that rest on speculation about the decisions of independent actors," *Clapper*, 568 U.S. at 414. And here, FDA's determinations simply resulted in the elimination of a *federal* requirement that the drug be dispensed in person; it does not cause any provider to thwart state restrictions.

The States' theory—that their own sovereign interests allow them to challenge FDA's actions based on decisions made by individuals *in other states*—flips federalism principles on their head. In essence the States' argument posits that, since they have chosen to restrict their citizens' access to abortion medication while other sovereign states have opted to protect that access, and because state residents can cross state lines to obtain medication or receive it through the mail, the States are harmed by those other states' more-permissive rules and thus have the right to block those *other states'* policy choices by suing to enjoin FDA's actions nationwide. That theory is inconsistent with our federalist system. For instance, states have made widely differing judgments about the availability of, *e.g.*, fireworks—but a state seeking to clamp down on fireworks coming across its border cannot sue to halt sales nationwide, including in states where they are legal. The

States' disagreement with abortion does not allow them to "impose [their] own policy choice on neighboring States." *BMW of N. America, Inc. v. Gore*, 517 U.S. 559, 571 (1996).

3. The States cannot assert a quasi-sovereign interest in protecting citizens in a suit against the federal government.

The States also allege harm to their "quasi-sovereign interest in protecting the health and welfare of women and girls." Prop. Compl. ¶ 343. But that argument runs headlong into the well-established rule that States cannot assert *parens patriae* interests against the federal government.

The Supreme Court has repeatedly and recently emphasized that States cannot assert their citizens' rights in a suit against a federal agency, "because '[a] State does not have standing as *parens patriae* to bring an action against the Federal Government.'" *Haaland v. Brackeen*, 143 S. Ct. 1609, 1640 (2023) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982)). The States' asserted interest in preventing harm to their citizens is directly analogous to the interest held insufficient for standing in *Brackeen*—there, a state's interest in safeguarding the constitutional rights of "non-Indian families," *Id.*. at 1640 n.11. The Supreme Court described the state's reliance on that interest as "a thinly veiled attempt to circumvent the limits on *parens patriae* standing." *Id.* So too here; indeed, the States make no attempt to explain how their reliance on an "interest in the health and well-being … of its residents in general," Prop. Compl. ¶ 343 (quotation omitted), could be reconciled with the black-letter principle that, although a state can "under some circumstances" sue a nonfederal entity "for the protection of its citizens," "it is no part of its duty or power to enforce their rights" against "the Federal Government" because "it is the United States, and not the State, which represents them." *Snapp*, 458 U.S. at 610 n.16.

4. The States lack standing to challenge the 2019 approval of generic mifepristone.

As set forth above, none of the States' alleged injuries is sufficient to establish standing. But the States' efforts to challenge FDA's 2019 approval of the generic version of mifepristone fail for an additional reason as well: The States fail to introduce any "evidence that the 2019 Generic Approval contributed to any … injury sustained by" the States. *All. for Hippocratic Med.*, 78 F.4th at 241. The States (and a purported expert declaration they attach) invoke principles of supply and

demand, suggesting that "[b]y approving a generic version of the drug, FDA increased supply and availability, lowering cost and thus increasing use of chemical abortions." Prop. Compl. ¶ 257; States' App'x, ECF No. 151-3, at 648-52. That is still only an attempted *statistical* showing of harm, and such probabilistic arguments are inadequate to establish concrete, imminent injury even at the motion to dismiss stage. *See, e.g.*, *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009). Because the States cannot identify any past or future injury that is definitively tied to FDA's approval of generic mifepristone, the States lack standing for this claim even if their injuries were otherwise cognizable.

II. The States Meet None of the Criteria for Intervention as of Right

Contrary to the States' assertions, they have neither an "absolute" nor "unqualified right to intervene" in this action, Mot. at 6-7, because they fail to establish entitlement under any of the requisite factors. *See* Fed. R. Civ. P. 24(a)(2). The States' proffered excuses for their year-long delay in seeking intervention lack merit since any stake they may have in the outcome of this litigation has been plain from the outset (indeed, all three States already have participated before this Court as *amici curiae*, *see* ECF Nos. 48-2 (Missouri), 100 (Idaho and Kansas)), and the intervening events purportedly prompting the States' request did not materially change any interest. Intervention at this stage, when FDA already has secured a full stay of this Court's order and the Supreme Court has granted certiorari, would be highly prejudicial to the government and would be pointless since it would not allow the States to participate in Supreme Court proceedings. Moreover, the States lack any concrete interest sufficient to challenge FDA's actions, and even if they could show such an interest, disposition of this case (on grounds of standing or otherwise) would not, "as a practical matter, impair or impede [their] ability to protect that interest," *Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Comm'n*, 834 F.3d 562, 565 (5th Cir. 2016) (citation omitted), since it would not prevent the States from filing their own action in a proper venue. And finally, the States' claim that the existing Plaintiffs cannot adequately represent their interests is belied by their own characterization that their "complaints materially differ only with respect to the theories of standing," *see* ECF No. 156, States' Opp. to Mot. to Hold in Abeyance, at 2, and the States do not rebut the presumption of adequate

representation that applies in such circumstances. In short, the States have failed to establish any of the factors for intervention as of right and their motion should be denied.

A. The States' delay is fatal to their request.

In evaluating whether the States timely have sought to intervene, the Court must consider the so-called *Stallworth* factors:

> (1) The length of time during which the would-be intervenor actually knew or reasonably should have known of its interest in the case before [it] petitioned … to intervene … ; (2) [t]he extent of the prejudice that the existing parties to the litigation may suffer as a result of the would-be intervenor's failure to apply for intervention [sooner] … ; (3) [t]he extent of the prejudice that the would-be intervenor may suffer if … interven[tion] is denied; and (4) [t]he existence of unusual circumstances militating either for or against a determination that the application is timely.

Stallworth v. Monsanto Co., 558 F.2d 257, 264-66 (5th Cir. 1977) (citations omitted). The States have not acted with the diligence necessary to support a finding of timeliness under any factor.

i. No intervening events have altered the States' interest in this suit, so any purported interest has been present since the outset.

Although the States are correct that, under Fifth Circuit precedent, timeliness "is *not* [necessarily] measured from the date an intervenor would have first become aware of the litigation," Mot. at 8, the authorities on which the States rely do not support their gambit. "The timeliness clock runs either from the time the applicant knew or reasonably should have known of his interest [in the litigation itself], or from the time he became aware that his interest would no longer be protected by the existing parties to the lawsuit." *Edwards v. City of Houston*, 78 F.3d 983, 1000 (5th Cir. 1996). In practice, this requires courts to consider the date at which the would-be intervenor had reason to believe the outcome of the litigation may "adversely affect[]" the movant's interests. *Sierra Club v. Espy*, 18 F.3d 1202, 1206-07 (5th Cir. 1994). As explained more fully below, each of the authorities on which the States rely involve situations where a party promptly moved for intervention within weeks of an event that newly gave rise to the party's interest. Given that a full year has elapsed since Plaintiffs filed this suit, the States can show that their delay in filing was reasonable only by

establishing that some intervening, far-more-recent event provided notice that their interests could be adversely impacted.

The States insist that "[i]t was not until very recently that [they] were put on notice that their interests may be adversely affected" by this suit and proffer three purportedly intervening events that, they claim, provide the appropriate start date for the timeliness clock. Mot. at 9. But none of these events materially changed any interest the States could have vis-à-vis *this litigation*—meaning that any interest the States could have in its outcome did not newly arise this summer. First, the States point to a June 2023 release of information, "the first since after *Dobbs*—showing just how many Missourians are obtaining chemical abortions in Kansas before going back home to Missouri." *Id.* But the States' portrayal is misleading: The report on which they rely shows that "2,883 Missourians obtained abortions in Kansas"[1] in 2022, yet the States ignore that this number represents a substantial *drop* in abortions performed in Kansas for Missouri residents, since 3,937 such abortions were recorded in 2021[2] and 3,641 were recorded in 2020.[3] Data revealing that the number of Missourians obtaining an abortion in Kansas *decreased by 27%* did not newly reveal any interest by Missouri in the outcome of this litigation (and Kansas cannot complain about out-of-state residents crossing its borders to pursue activity therein that is perfectly lawful). Besides, in 2020 only 167 abortions were performed within Missouri compared to more than 3,000 performed in Kansas for Missouri residents,[4] so both states have long been aware that Missouri residents primarily obtained abortion services in the neighboring state.

Second, the States claim to have newly discovered an interest in this litigation through news reports "that out-of-state organizations are sending thousands of abortion pills into Intervenor States," Mot. at 9. These news reports have nothing to do with the issues in this litigation. But in any event, the States themselves plead that organizations have been sending mifepristone through

[1] Abortions in Kansas, 2022 Preliminary Report at 8, https://perma.cc/L5XC-4JT2 (cited Mot. at 5).
[2] Abortions in Kansas, 2021 Preliminary Report at 8, https://perma.cc/3CQ6-SFNE.
[3] Abortions in Kansas, 2020 Preliminary Report at 8, https://perma.cc/2BT8-DENC.
[4] *Nearly half of abortions in Kansas are for Missouri residents*, THE KANSAS CITY BEACON, Nov. 17, 2021, https://perma.cc/H5HA-5GCK.

the mail since at least 2018, *see* Mot. at 4, and the possibility that some patients in abortion-restrictive states have sought mifepristone through such channels was widely publicized even before this suit was filed. *See, e.g.*, *To get banned abortion pills, patients turn to legally risky tactics*, THE WASHINGTON POST, July 6, 2022, https://perma.cc/K8Z9-VV35; *Mail-order abortion pill requests surged after Roe reversal, study finds*, AXIOS, Nov. 1, 2022, https://perma.cc/6BDZ-3Z9D. The States cannot establish notice of a newly acquired interest in this suit by selecting two more-recent news reports while ignoring similar reports that publicized the same alleged facts far earlier.

Even aside from publicly available information, the States themselves have articulated this alleged interest far earlier. For instance, in its February 2023 *amicus* brief, Missouri told this Court that it "has a strong interest in this litigation because the FDA's decision to … create a regime of abortion by mail imposes harms that necessarily spill over into Missouri, impeding the operation of state law." ECF No. 48-2, Br. of the State of Missouri as Amicus Curiae, at 1; *see also id.* at 7 (alleging FDA has "purport[ed] to create a nationwide license to distribute chemical abortion drugs by mail"). Idaho and Kansas likewise took the same position before this Court in February 2023. *See* ECF No. 100, Br. of 22 States as Amici Curiae, at 13 (arguing that FDA's actions "impose a federal mail-order abortion regime that disregards the protections for life, health, and safety adopted by numerous States' elected representatives"). Indeed, Idaho even sought to intervene in March 2023 in separate litigation to press the same interest it now claims to have only just learned about. *See* States' Prop. Compl. in Intervention, ECF No. 76-1, *Washington v. FDA*, Case No. 1:23-cv-03026 at ¶ 52 ("Idaho also has a sovereign interest in ensuring that its laws are enforced and not undermined" but, "without the in-person dispensing requirement, mifepristone will be able to travel across Idaho's borders and be used to unlawfully induce abortions in Idaho"). The States could not have newly discovered this summer an interest that they repeatedly articulated in court filings far earlier.

Third, the States invoke an out-of-circuit motion to dismiss ruling in unrelated litigation, which they claim has "recently" revealed "a substantial and serious sovereign harm" necessitating participation in this litigation. Mot. at 3. In that case, *GenBioPro, Inc.*, 2023 WL 5490179, a district court allowed to proceed a preemption claim challenging West Virginia's in-person dispensing

requirement. But similar preemption issues are not even presented by this litigation—and the States wholly ignore that in October 2023, before they filed their motion to intervene, the plaintiff in *GenBioPro* amended its complaint to abandon this particular preemption claim and dismiss it with prejudice. *See* Mot. Am. Compl. & Jt. Stip., *GenBioPro v. Sorsaia*, ECF No. 73 at 2. The States' reliance on that ruling to support their belated intervention here is meritless given that the States plainly were aware of the case (which was filed in January 2023) well before this summer, since all three participated as *amici curiae* in February 2023; the only preemption claim that survived the motion to dismiss has now been dismissed with prejudice; any potential dispute over preemption of the States' laws is purely hypothetical and speculative, since no such challenge has been raised; and in any event, the States themselves insist that the *GenBioPro* ruling was wrong, *see* Compl. ¶ 324. That non-binding, preliminary ruling in unrelated litigation did not newly create an interest by the States in the outcome of this litigation.

The States' reliance on these three purported intervening events is illusory because none created or revealed any newfound interest by the States in the outcome of this litigation. And since the States cannot identify any interceding event marking "the time [they] knew or reasonably should have known of [their alleged] stake" in this lawsuit, *John Doe No. 1 v. Glickman*, 256 F.3d 371, 376 (5th Cir. 2001), any purported interest in it necessarily would have "materialized," *id.* at 377, at the commencement of the litigation—as proven by the States' earlier *amici curiae* filings.

The States' request bears no resemblance to the circumstances present in the cases on which they rely. On the contrary, in each case the Fifth Circuit identified a specific event precipitating the need for intervention and found timely a request to intervene filed within *weeks* of that event. In *Glickman*, for instance, precisely the same issue was presented in litigation pending in both Waco and the District of Columbia. 256 F.3d at 377-78. But not until the D.C. court stayed that action pending resolution of the Waco matter, "ma[king] it clear that the Waco Lawsuit would be the lawsuit where the Issue would be decided," did the D.C. plaintiffs' stake in intervening materialize. *Id.* Because the D.C. plaintiffs sought intervention within one month after becoming aware of their stake in the Waco litigation, the Fifth Circuit determined intervention was timely. Similarly, in *Espy*,

intervention was deemed timely in a roughly eight-year-old lawsuit after an unanticipated preliminary injunction issued *and* the Forest Service announced "that it would apply the preliminary injunction to all timber sales (not merely the nine sales challenged by the plaintiffs)," thus signaling that it "would not protect the[] interests" of would-be purchasers in separate, unchallenged sales. 18 F.3d at 1206-07 (noting that intervention was sought less than two months after intervenor's interest newly materialized). And in *Edwards*, third parties lacked notice of their interest in civil-rights litigation against the city of Houston until the trial court entered a consent decree with a "broad reach" directly impacting intervenors' members, who then timely sought intervention "only 37 and 47 days … after publication of the notice and decree." 78 F.3d at 1000. Likewise, in *Stallworth*, a challenge by African-American employees to certain promotion and seniority practices of the defendant company, other employees timely moved to intervene less than one month after the district court entered a sweeping consent order under which intervenors "were moved to lower paying jobs." 558 F.2d at 261-62, 267 ("It cannot be said that they ought to have fathomed the potential impact of this admittedly complex case on their seniority rights at some earlier date.").[5] The common thread in these cases is that, in each, the Fifth Circuit identified some intervening event that newly gave rise to an interest by intervenor in the outcome of the litigation—and, each time, intervenors promptly acted in less than two months. Here, by contrast, the States have failed to identify any comparable event that materially changed their purported interests, meaning any interest they could have remains unchanged from the outset, and since the States chose to sit on the sidelines for roughly a year, their request is untimely.[6]

[5] *See also Ross v. Marshall*, 426 F.3d 745, 755 (5th Cir. 2005) (intervention timely sought by insurer to appeal final judgment against named insured; intervention sooner "would have been pointless as" intervenor's interests were being protected by counsel for named insured paid for by insurer).

[6] The States' contention that their year-long delay in acting "should be judged against the fact that this case still remains in its earliest stages" because FDA "ha[s] not even filed an answer," is unsupported by the precedent on which they rely and unpersuasive, since the States fail to identify any event newly giving rise to an interest in this suit and have not acted within two months of any interest arising. Mot. at 9. As for the fact that no answer has been filed, this case has been stayed for an extended period while the government has sought review of the Court's preliminary injunction, including two trips to the U.S. Supreme Court; that unusual posture does not justify the States' tardy actions.

ii. *Intervention would prejudice the parties.*

The States' argument regarding prejudice to the existing parties rests on two flawed premises. Mot. at 9-11. First, the States once again contend that "the 'starting' point at which any prejudice is measured is the end of August," *id.* at 10, when a district court in West Virginia issued a motion to dismiss ruling in unrelated litigation with no merits issues in common with this litigation. But—as demonstrated *supra*—*GenBioPro* has neither created nor revealed any interest by the States in this litigation, so the prejudice prong must be measured against the States' delay since the suit was filed in November 2022. Second, the States contend that "[t]he lack of any substantive activity *before this Court* since April demonstrates that no party is prejudiced," Mot. at 10 (emphasis added), but this ignores that the parties vigorously have been litigating an appeal of this Court's order, both before the Fifth Circuit and the U.S. Supreme Court, since the order issued. The States cite no authority or rationale suggesting that proceedings on appeal do not count in the prejudice analysis.

FDA would suffer substantial prejudice if intervention is granted at this late date. The States base their need for intervention on the fact that FDA's recent petition for certiorari maintains its position that the existing Plaintiffs lack standing (an argument consistently pressed since the start of this case, *see* ECF No. 28, Defs.' Opp. to Mot. for Prelim. Inj., at 8-15), and insist that intervention promotes efficiency because, even if the Supreme Court agrees with FDA on standing, the States could carry this case forward. Mot. at 1-2. But in those circumstances, FDA will be forced to expend significant resources to litigate the States' ability to maintain this suit notwithstanding the lack of jurisdiction at the outset, *see supra* § I. And in the scenario posited by the States, in which FDA prevailed on standing but this Court allowed the States to proceed nonetheless, FDA plainly would be prejudiced by the inefficiency of being forced to relitigate precisely the same issues on remand in the same docket simply because the States had swooped in to proceed where the original plaintiff could not. While the States contend that "there is a serious risk of judicial inefficiency if not all … theories of standing" are "presented at once," Mot. at 1, the States are responsible for creating that state of affairs by sitting idly by until the case is teed up for the Supreme Court. Nor can the States seriously contend that their last-minute effort to intervene "alleviates prejudice to the Defendants"

by obviating the need to respond to a separate lawsuit, *see* Mot. at 10-11; the States cannot alleviate the prejudice caused by their belated request by claiming that purported efficiency is in the best interests of FDA—when it is they who seek to evade venue, statute of limitations, and other threshold requirements by piggybacking onto Plaintiffs' claims.[7]

iii. The States would suffer no prejudice because they can file suit in an appropriate forum.

The States' assertion that they would suffer "significant prejudice to [their] ability to protect their rights and interests" absent intervention, Mot. at 11, is incorrect. Once again, the premise of the States' request is that the Supreme Court could agree with FDA that the existing Plaintiffs lack standing, but that would have no impact on the States' ability to protect their alleged interests. Prejudice to a would-be intervenor occurs where the outcome of the litigation will bind or adversely impact the would-be intervenor in a concrete way and, absent intervention, the proposed intervenor would lack recourse to protect its interest. *See, e.g.*, *Glickman*, 256 F.3d at 379 (intervenor would be prejudiced where, if existing plaintiff prevailed, "the USDA will be prohibited, by court order, from disclosing the … Information that the [intervenor] seeks" in separate litigation); *Espy*, 18 F.3d at 1206-07 (intervenor was prejudiced by Forest Service's decision to apply preliminary injunction broadly to circumstances not at issue in litigation); *Ross*, 426 F.3d at 756 (intervenor "will suffer considerable prejudice if it is denied the opportunity" to participate where it "is bound by the district court's judgment" that "may expose it to significant liability"). As these cases make clear, a putative intervenor must show that an adverse outcome of the subject litigation will *prevent* it from vindicating its rights. But here, the States are free to file their own lawsuit in an appropriate venue. Indeed, even in the scenario purportedly prompting their request—an adverse ruling rejecting the existing

[7] Although the States' proposed Complaint could be read to raise a broader challenge than the existing Plaintiffs to the 2019 approval of the generic version of mifepristone, *i.e.*, challenging the underlying science supporting that approval, *compare* Pls.' Compl. ¶¶ 384-388 (challenging the 2019 approval based solely on the name-brand drug's approval in 2000 as being unlawful), *with* Prop. Compl. ¶ 414 ("FDA's 2019 ANDA Approval was independently unlawful because FDA lacked a sufficient scientific basis for granting the approval."), FDA assumes that is not their intent, given the States' insistence that they raise the same substantive arguments as the Plaintiffs. But if that understanding is mistaken, it is one more reason to deny intervention, given the prejudice that would accrue to FDA from expansion of the scope of this litigation.

Plaintiffs' standing—that could not conceivably "prejudice the ability of the States to litigate their interests" in a proper forum, *contra* Mot. at 11.

iv. *The unusual procedural posture militates against a finding of timeliness.*

Finally, the Court must evaluate any unusual circumstances that weigh in favor of or against a finding of timeliness. *Espy*, 18 F.3d at 1207. The course of this litigation has been far from typical: Despite the fact that the government has yet to answer Plaintiffs' complaint, this matter is before the Supreme Court for the second time. That Court previously granted FDA's request for an emergency stay of this Court's order—necessarily meaning that FDA had demonstrated a likelihood of success on the merits of its appeal—with the result that the stay order never has taken effect, and the Court will consider the case this term. Furthermore, the States have participated as *amici curiae* both in this litigation and in the *GenBioPro* litigation which they claim forms a basis for the need to intervene now. The States' complaint that their chosen method of participation to date now affords them insufficient protection rings hollow considering their delay in moving for intervention. This unique procedural history and the current posture of the case weigh strongly against a finding of timeliness. Because each of the *Stallworth* factors weighs against a finding of timeliness, the States have failed to justify their year-long delay in seeking intervention.

B. The States have not demonstrated an interest in this litigation.

Not only have the States failed to act in a timely manner, they also lack a legally protected interest sufficient to warrant intervention. The States treat this factor as essentially coextensive with Article III standing and argue that their allegations of economic harm, threat to sovereign interests in enforcing their legal codes, and *parens patriae* interest in protecting citizens' health provide an adequate basis to support their participation in this litigation. Not so: As explained *supra* Section I.B, each of the States' three theories of standing fail as a matter of law.

Moreover, the interest analysis is not, as the States portray, a simple inquiry into whether a party has standing. *See United States v. 36.96 Acres of Land, More or Less*, 754 F.2d 855, 859 (7th Cir. 1985 ("There is a qualitative difference between the 'interest' which is sufficient for standing to bring an action under the APA and the 'direct, significant legally protectable interest' required"

under Rule 24(a)). Circuit precedent requires a would-be intervenor to demonstrate that it has "a stake in the matter that goes beyond a generalized preference that the case come out a certain way." *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015). An asserted interest must be one that impacts the party in a "direct" manner, *id.* at 658; it is insufficient when the movant "seeks to intervene solely for ideological, economic, or precedential reasons; that would-be intervenor merely *prefers* one outcome to the other." *Id.* at 657; *see also Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 972 (3d Cir. 1998) ("[I]ntervenors should have an interest that is specific to them, is capable of definition, and will be directly affected in a substantially concrete fashion by the relief sought"—an interest that "may not be remote or attenuated"). That analysis focuses on whether the asserted interest is "specific to the person possessing the right," *Texas*, 805 F.3d at 658, rather than a generalized or broadly-shared preference that the issue result in a certain outcome.

The States cannot meet this test because the interests they assert—even were they legally cognizable, which they are not—are precisely the sort of broad-based "ideological" and "economic" motivations that are insufficient to support intervention. A final judgment in this case, whether for or against the existing Plaintiffs, will have no *direct* impact on the States. The attenuated purported harms relied on by the States are indistinguishable from the interests of other states that provide some type of funding for healthcare and/or oppose abortion on ideological grounds. Nor, for that matter, are the States' purported interests different in kind from those of states that *do* support abortion access—in neither instance is the generalized preference that this litigation result in a certain outcome sufficient to support intervention. After all, the States here are seeking intervention *as of right*; if their attenuated theories sufficed, any state wishing to protect abortion access or any healthcare providers desiring to continue prescribing mifepristone would have equally protected interests. That is not the law.

For example, the *en banc* Fifth Circuit rejected an attempt by a governmental entity to intervene in a contract dispute between a private utility company and its fuel supplier to assert an interest in maintaining low electricity rates, which the intervenor claimed would rise if the utility lost the underlying dispute. *New Orleans Pub. Serv., Inc. v. United Gas Pipe Line Co.*, 732 F.2d 452, 460-61

(1984). Even though the threat of higher prices might injure the would-be intervenor, it did not support intervention: "By requiring that the applicant's interest be not only 'direct' and 'substantial,' but also 'legally protectable,' it is plain that something more than an economic interest is necessary. What is required is that the interest be one which the *substantive* law recognizes as belonging to or being owned by the" intervenor. *Id.* at 464. This forecloses the States' endeavor, which relies on precisely the same sort of undifferentiated economic and ideological harms.

The States also rely on *Wal-Mart Stores*, 834 F.3d 562, to contend that, "[s]o long as a party 'can legally protect' a regulatory system affected by a lawsuit, 'it likely has an interest' for the purpose of intervention." Mot. at 13. This represents a fundamental misreading of *Wal-Mart Stores*. There the Fifth Circuit confirmed the settled proposition that "the *intended beneficiary* of a government regulatory system" may in some circumstances intervene to *defend* that regulatory regime when challenged by an outside party. *Wal-Mart Stores*, 834 F.3d at 569 (emphasis added). In other words, where relief is sought directly against a statutory or regulatory scheme that was passed for the benefit of certain private individuals or entities, the intended beneficiaries of that scheme may protect a legally cognizable interest in its maintenance. *See id.* at 566-69 (surveying caselaw standing for that proposition). Here, none of the States' regulatory systems are challenged in this lawsuit; no party is seeking relief against any aspect of the States' legal codes; and it is *the States themselves*, not Plaintiffs, that wish to inject issues related to their regulatory systems into this dispute.[8]

[8] *Heaton v. Monogram Credit Card Bank of Georgia*, 297 F.3d 416, 424 (5th Cir. 2002) (cited Mot. at 13), is equally irrelevant. There the court merely confirmed that a governmental entity can intervene in an otherwise private dispute to defend its regulatory decisions when challenged in the underlying litigation. *Heaton* supports no more than the uncontroversial proposition that the States could intervene in litigation challenging the legality of their abortion laws; it does not support their attempt to intervene here on the purported basis of defending state-law regulatory systems against which no relief has been sought. Equally far afield is *Sierra Club v. City of San Antonio*, 115 F.3d 311, 315 (5th Cir. 1997) (cited Mot. at 14), since there the state intervenor asserted sovereign interests in the oversight and management of state natural resources that were directly at issue in the underlying litigation. It is well-established that a state has a right to be heard in a dispute over management of its own natural resources. No precedent cited by the States is analogous to their intervention attempt here.

C. The outcome of this matter will have no bearing on the States' interests.

This factor is easily dispatched. The very premise of the States' intervention motion is that they are concerned that the existing Plaintiffs might not have standing to pursue their claims. *See, e.g.*, Mot. at 1-2 ("if an appellate court vacates the preliminary injunction *on standing grounds*, or this Court declines to grant permanent injunctive relief *on standing grounds*, the States' interests will be harmed." (emphasis added)); *see also id.* at 5 (arguing that, "if the Supreme Court agrees with the Federal Government's standing arguments, then the States will lose whatever incidental relief they have obtained incident to" this Court's order). But a loss on standing by the existing Plaintiffs plainly would not impede the States' ability to protect their asserted interests. A ruling on the Plaintiffs' standing would have no "*stare decisis*" effect on the States or in any future action by the States, *contra* Mot. at 15-16. Under the States' own premise, therefore, intervention is not needed to protect their asserted interests.

Nor can the States otherwise establish that the outcome of this litigation will, as a "practical … and not merely theoretical" matter, impair or impede the States directly, as is required for intervention as of right. *Brumfield v. Dodd*, 749 F.3d 339, 344 (5th Cir. 2014) (citation omitted). The States cannot establish that intervention is warranted to guard against a loss by the existing Plaintiffs *on the merits*, since they already have told this Court that "the substantive arguments in the complaints are the same" and that they "materially differ only with respect to the theories of standing." ECF No. 156, Opp'n to Mot. for Abeyance, at 2. The States cannot identify how the existing Plaintiffs might be deemed to have standing but lose on the merits yet the States would nonetheless succeed on the same "substantive arguments," *see id.*, in the same proceeding.

Indeed, the States do not claim that their participation is likely to alter any outcome on the merits, yet they rely on cases that found a would-be intervenor's interests could be impaired by the "*stare decisis* effect of the district court's judgment." Mot. at 15. But the States overlook that, in each of those cases, the outcome of the suit stood to *directly impact* the intervenor, who would have no opportunity to present its own claims or otherwise vindicate its interest in a separate lawsuit. *See Espy*, 18 F.3d at 1207 (success by environmental groups would compel Forest Service to apply ruling

in a manner "threaten[ing] … existing timber contracts" of intervenors); *Heaton*, 297 F.3d at 424 (district court's decision in private litigation would overturn agency's regulatory decision with no opportunity to correct). A mere interest in the development of precedent, or the desire to assert a claim that might be affected by a Supreme Court decision in another case, does not justify intervention as of right under Rule 24(a).

"[A]s a practical matter," then, resolution of this action cannot "impair or impede the movant's ability to protect [its] interest," *Brumfield*, 749 F.3d at 344, since a ruling on standing would not apply to the States; resolution of the merits, if reached, will not differ with the States' participation; and nothing prevents the States from filing their own lawsuit in a proper forum. This distinguishes the States' attempt from every case on which they rely, each of which involved scenarios where an adverse ruling would act concretely and directly on the intervenor's rights with no recourse after such a judgment. *See id.*, 749 F.3d at 344 (if United States succeeded in enjoining state school-voucher program, "some parent[intervenors] are at risk of losing vouchers or their full range of school choices"); *Espy*, 18 F.3d at 1207 (defendant Forest Service's decision to apply injunction broadly to all timber sales, not only those challenged in underlying litigation, would bar intervenors' existing contracts); *Ross*, 426 F.3d at 760 (intervenor insurance company would face liability exposure from judgment against named insured); *see also Glickman*, 256 F.3d at 380 (absent intervention, movant "would be prevented from ever being heard in a lawsuit that has the potential to end its quest to compel the USDA to disclose" certain information and "that ruling could collaterally estop [movant] in" another court).

D. **The States have failed to rebut the presumption of adequate representation**.

On the final factor, adequacy of representation, the States argue that, since "an action brought by private plaintiffs cannot adequately represent governmental interests," Mot. at 16, the existing Plaintiffs cannot provide adequate representation. In other words, the States posit that, because their theories of harm vary—and since private parties could not assert sovereign harms—this factor is met. *See id.* ("some of the injuries [the States] seek to assert … specifically the sovereign harms … could *never* be asserted by private, non-state parties). The States' argument conflates the

representation analysis, which asks whether the litigation goals of parties are in alignment, with the question whether parties are relying on the same theories of injury. This is not the law; the States' theory would "write the requirement completely out of the rule," *Bush v. Viterna*, 740 F.2d 350, 355 (5th Cir. 1984), since distinct parties rarely present precisely overlapping theories of injury.

Contrary to the States' portrayal, the adequacy of representation analysis focuses on whether the existing parties seek the same goal or objective in the litigation as the would-be intervenor. Where the litigation goals align, the purported intervenor's interests are adequately represented; adequate representation does not exist, however, where the existing parties have some potential conflict of interest with the intervenor.

Here, the States' goal in this litigation is the same as Plaintiffs'—reimposing restrictions on mifepristone's distribution—and they cannot articulate *any* potential scenario in which their goals would conflict with Plaintiffs'. The States' request is thus fundamentally unlike the interests found to be inadequately represented in every authority on which they rely. *See City of San Antonio*, 115 F.3d at 315 (Texas's interest in maintaining adequate water supply state-wide not adequately represented by individual pumpers of aquifer, whose goals likely will "diverge" because they "rely on the … water supply for their immediate subsistence"); *Espy*, 18 F.3d at 1207-08 (Forest Service required to protect the public interest, not to "represent … the economic concerns of the timber industry," and already had taken position at-odds with intervenor's interest, demonstrating misalignment of goals); *Brumfield*, 749 F.3d at 346 (parents' interest in maintaining school vouchers not adequately represented by state, which had "many interests in this case" and was "staking out a position significantly different from that of" the parents); *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538-39 (1972) (because "t[]he statute plainly imposes on the Secretary [of Labor] the duty to serve two distinct interests … th[at] may not always dictate precisely the same" litigation outcome, Secretary could not adequately represent union member's individual interest); *Glickman*, 256 F.3d at 381 (USDA "must represent the broad public interest," which may not align with an individual FOIA requestor's goal of receiving information); *Edwards*, 78 F.3d at 1005 (City did not adequately represent interest of certain police officers due to "sharp disalignment" in litigation

goals). As these cases show, the States' reliance on the fact that Plaintiffs cannot assert "sovereign and direct economic harms … [to] the States," Mot. at 17, simply misstates the relevant test.

Indeed, in situations such as this "when the would-be intervenor has the same ultimate objective as a party to the lawsuit," the Fifth Circuit applies a "presumption of adequate representation." *Edwards*, 78 F.3d at 1005. "In such cases, the applicant for intervention must show adversity of interest, collusion, or nonfeasance on the part of the existing party to overcome the presumption." *Id.* This requires an intervenor to demonstrate "adversity of interest," meaning that its goals in the lawsuit "diverge from the putative representative's interests in a manner germane to the case." *Texas*, 805 F.3d at 661-62.

The States have not even attempted to meet their burden in overcoming the strong presumption of adequacy; nowhere have they asserted that the existing Plaintiffs are adverse to the States, are colluding with the government, or have negligently conducted this litigation. *Id.* Rather than attempt to carry their burden to rebut the presumption, the States largely dismiss this test by cherry-picking language from cases where an adversity of interest was found to apply. *See* Mot. at 18 (citing *Brumfield*, 749 F.3d at 345 (discussed *supra*)); *Wal-Mart Stores*, 834 F.3d at 569 ("Even assuming, *arguendo*, that … the presumption[] of adequate representation applies, the [intervenor] has shown 'adversity of interest'") (citation omitted); *see also Heaton*, 297 F.3d at 424-25 (FDIC's interest "in protecting the proper and consistent application of the Congressionally designed framework to ensure the safety and integrity" of the banking system could not be adequately represented by an individual bank "even though, at this moment, they appear to share common ground"). The States' portrayal of these cases as scenarios in which "the presumption has been found not to apply," Mot. at 18, is baseless; on the contrary, they represent successful showings of adversity of interest—a showing that the States make no attempt to satisfy. Indeed, the States *admit* that they seek to press the same substantive arguments as Plaintiffs, their proposed complaint demonstrates an alignment in their ultimate goals in this litigation, and they can articulate no scenario in which their interests would be adverse to Plaintiffs', which means, as a matter of law, that Plaintiffs adequately represent their interests.

III. Permissive intervention should be denied.

The States argue in the alternative that this Court should grant permissive intervention, but their arguments are derivative of their quest for intervention as of right and are equally unpersuasive. Permissive intervention can be granted only where an application is timely, Federal Rule of Civil Procedure 24(b)(1)(B), and "[t]imeliness under mandatory intervention is evaluated *more leniently* than under permissive intervention." *Rotstain v. Mendez*, 986 F.3d 931, 942 (5th Cir. 2021) (emphasis added). As demonstrated *supra* § II.A, the States have failed to show that their application is timely under the *Stallworth* factors, 558 F.2d at 266. Because the States have failed to demonstrate that their application is timely under the more-lenient standard for mandatory intervention, *Rotstain*, 986 F.3d at 942, their request for permissive intervention likewise is untimely. For similar reasons, the States have not shown that existing parties will not be prejudiced by intervention at this stage, *contra* Mot. at 20-21. And finally, in considering permissive intervention, this Court should "consider … 'whether the intervenors' interests are adequately represented by other parties' and whether they 'will significantly contribute to full development of the underlying factual issues in the suit.'" *New Orleans Public Svc., Inc.*, 732 F.2d at 472. The existing Plaintiffs adequately represent the States' interests, and the States' overlapping claims will in no way aid (or alter) factual development here.

In short, no factor supports permissive intervention, and the Court should decline to exercise its discretion to grant the States' request. Whatever the outcome in the Supreme Court, intervention by the States will only threaten to complicate and prolong this already-complex litigation. As discussed above, this Court will lack jurisdiction to allow the case to proceed if the existing Plaintiffs are found to lack standing (even if intervention is granted in the interim), so intervention cannot be justified in that scenario. And if the existing Plaintiffs *are* held to have standing and the case is remanded for further proceedings, participation by the States will inject new and difficult issues for resolution including the States' theories of standing and additional exhaustion issues, since the States make no claim to have presented their issues to the agency. Since participation of the States will only complicate these proceedings—and the States are free to sue in a proper forum—there is no reason for this Court to grant discretionary intervention.

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Respectfully submitted,

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